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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,332	03/14/2001	Keith P. Johnston	61112	3850

109 7590 06/12/2003

THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION
P. O. BOX 1967
MIDLAND, MI 48641-1967

EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,332

Applicant(s)

JOHNSTON ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Extension of Time and the Request for Continued Examination, both received by the Office April 4, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, and 4-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,985,248 to Gordon. Applicant is claiming a method for preparing particles of a poorly water soluble drug by dissolving the drug in an organic solvent, spraying the mixture into an aqueous solution, and evaporating the organic solvent.

Gordon teaches a method for preparing dry powders having hydrophobic and hydrophilic components by combining solutions or suspensions of the components and spray drying them simultaneously in a spray drier. More specifically, Gordon teaches dissolving a hydrophilic excipient in an organic solvent or cosolvent system, dissolving a hydrophobic drug in the same organic solvent or cosolvent system to produce an organic solution, and spray drying the solution to form particles comprising a mixture of the hydrophilic and hydrophobic components (claim 1). Furthermore, Gordon teaches that the process produces droplets of a liquid medium which are dried in a drying operation, which results in the formation of discrete particles (column 7,

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lines 1-10). Additionally, Gordon teaches the inclusion of excipients, such as povidone (column 5, lines 61-64). Furthermore, Gordon teaches the process will result in ultrafine particles, such as those with a size of less than 10 microns (column 6, line 4). Gordon further teaches that the particles are dispersible, if necessary for administration (column 6, line 58). Gordon also discusses the composition which results from his claimed method.

Applicant has amended the claims to include "wherein the drug/ organic mixture is sprayed at or below the liquid level of the aqueous solution." The examiner asks applicant to discuss the criticality of such a limitation. It is unclear to the examiner what this limitation does to render unexpected results to the process. Furthermore, it is not apparent that this limitation changes the resulting product in any way. It is recommended that applicant provide evidence discussing and demonstrating the criticality of this new limitation.

It is the position of the examiner that one of ordinary skill in the art would have looked to the teachings of Gordon for a method of preparing dry powders. Applicant has provided no scientific evidence that the teachings of Gordon are patentably distinct from the teachings of applicant. It is requested that applicant provide more discussion of any significant differences between the teachings of Gordon and applicant.

For the above reasons, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant has amended the claims to include a limitation reciting, "wherein at least one particle stabilizer is originally present in the aqueous solution, the drug/ organic mixture or both the

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aqueous solution and the drug/ organic mixture.” It is the position of the examiner that this newly added limitation does not distinguish the instant claims from the prior art. Applicant’s claim 4 states that the stabilizer can be a polymer. Gordon clearly teaches that hydrophilic excipients discussed in their composition can include polymers and other additives (c 5, l 61-64). This clearly reads on Applicant’s new limitation.

Applicant again argues that Gordon does not teach spraying the drug/ solvent mixture at or below liquid level of the aqueous solution. Previously, the examiner asked Applicant to state the significance of spraying below the liquid level. Applicant has stated in the response that this permits evaporation of the solvent while the water remains behind, such that the stabilizers remain solvated by the water, even as the organic solvent is evaporated. First, this statement would be more persuasive if presented in declaration form. Second, this statement is not commensurate in scope with the instant claims. The claims, as written, discuss spraying at or below the liquid level. However, Applicant has only discussed spraying below the liquid level. Therefore, no criticality has been placed on spraying at the liquid level, nor has any evidence been provided confirming that the cited reference does not teach such a limitation. For these reasons, the above rejection is maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
June 11, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
